Bariatric Outcomes
and Obesity Modeling

Study Meeting

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
This study sought to (1) define the clinical impact and economic burden of bariatric surgical procedures, and (2) estimate the cost-effectiveness and budgetary impact of obesity treatments when compared to no surgical intervention. We developed a cost-effectiveness model and a payer-based budget and fiscal impact tool to compare bariatric surgical procedures to non-operative approaches for maorbid obesity. Use of these economic models based on data from the Department of Defense (DOD) population found that all evaluated surgical interventions were cost-effective compared to non-surgical interventions. These economic assessments models can inform helath policy decisions related to obesity.

15. SUBJECT TERMS
Bariatric Surgery, Cost Effectiveness, Surgical Outcome

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Study Objectives

David Flum, MD, MPH, Co-Principal Investigator

Sean Sullivan, PhD, Co-Principal Investigator

OBJECTIVE 1 -

- Cost and Burden of Obesity Care
  - Quantify the burden of non-surgical costs across the U.S.
  - Quantify the burden of surgical costs across the U.S.

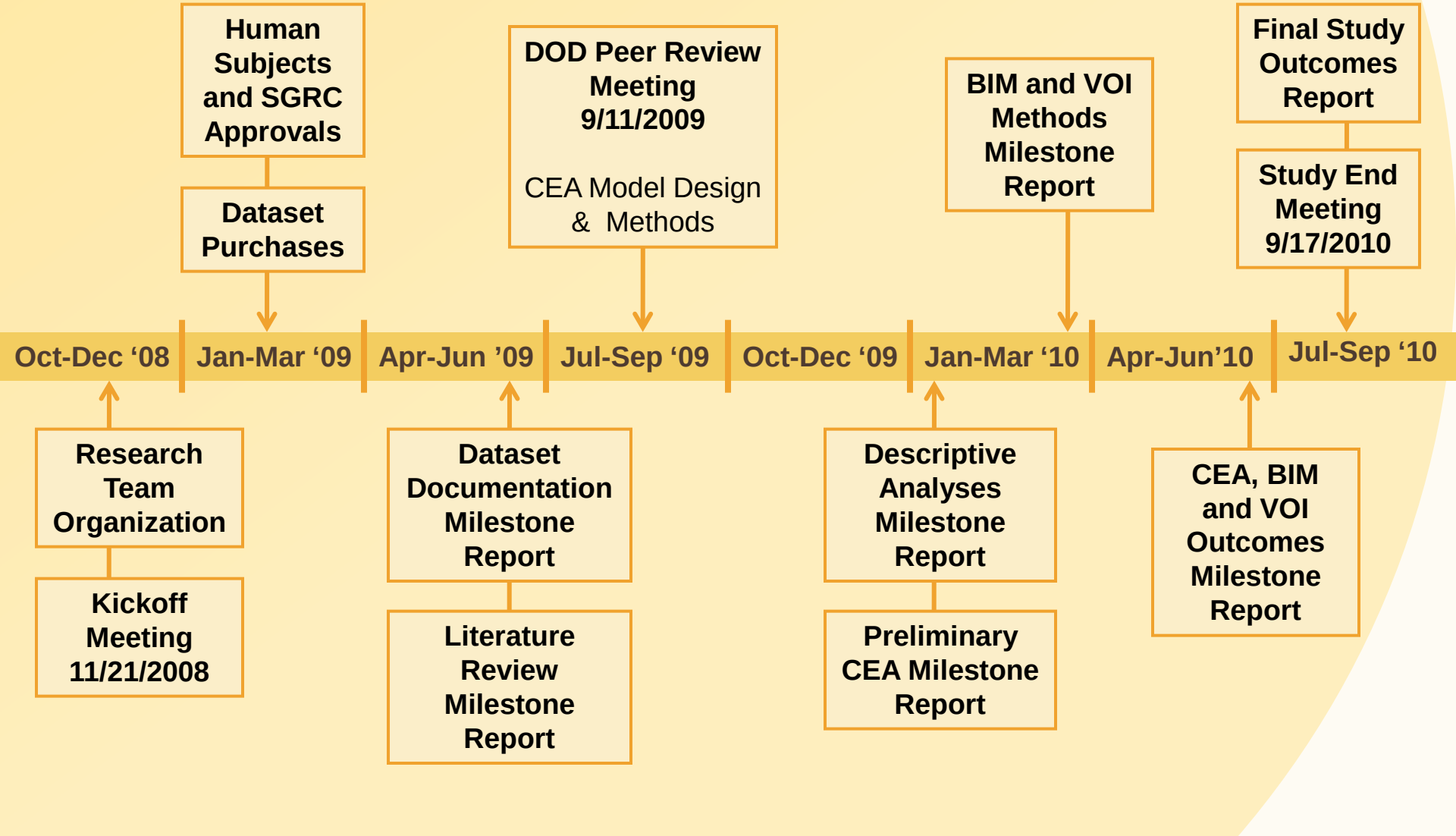
OBJECTIVE 2-

- Economic Assessment & Policy Planning
  - Macro-economic assessment of the development of healthcare policy related to obesity
  - Micro-economic tool to compare and contrast surgical care to non-surgical care based on patient characteristics
  - Undertake uncertainty and probabilistic sensitivity analysis, as well as value of information (VOI) computations, as appropriate

Study Milestones

Allison Rhodes, MS

BOOM STATEMENT OF WORK



Cost-Effectiveness and Budgetary Impact Models

Bruce Wang, PhD

CONSTRUCTING TWO ECONOMIC MODELS

- Cost-Effectiveness Model: Cost-effectiveness analysis (CEA) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action.

- Budget Impact Model: The purpose of a Budget Impact Analysis (BIA) is to estimate the financial consequences of adoption and diffusion of a new health care intervention within a specific health care setting or system context given inevitable resource constraints.

COST-EFFECTIVENESS MODEL OVERVIEW

- Two parts: 1) Decision Tree and 2) Natural History Model
- Results: Bariatric Surgery is cost-effective compared to no intervention

SIMPLICITY IN END-USER INTERFACE

Select Patient for Simulation:

Gender	○ Male ◉ Female	2
Age	40	
BMI	42	

Other inputs:

Discount Rate (Cost)	0.0%	
Discount Rate (QALY)	0.0%	
Threshold ($/QALY)	$ 100,000	

OUTCOMES

Intermediate Outcomes (5 years later)				
Intervention:	Patient Age	BMI	Costs	QALYs
Lap RYGB	45	29.40	$ 64,910.01	4.92
Lap Band	45	33.60	$ 68,626.00	4.78
Open RYGB	45	29.40	$ 77,563.49	4.92

Lifetime Outcomes				
Intervention	None	Lap RYGB	Lap Band	Open RYGB
Costs	$ 407,936.36	$ 420,589.35	$ 433,445.79	$ 433,242.82
QALY	40.61	45.06	43.98	45.06
Expected Age of Death	77	82	81	82
ICER		2,840.35	7,563.95	5,680.81
Net Benefit		432,819.62	311,740.74	420,166.14

ICER plane | Graphs

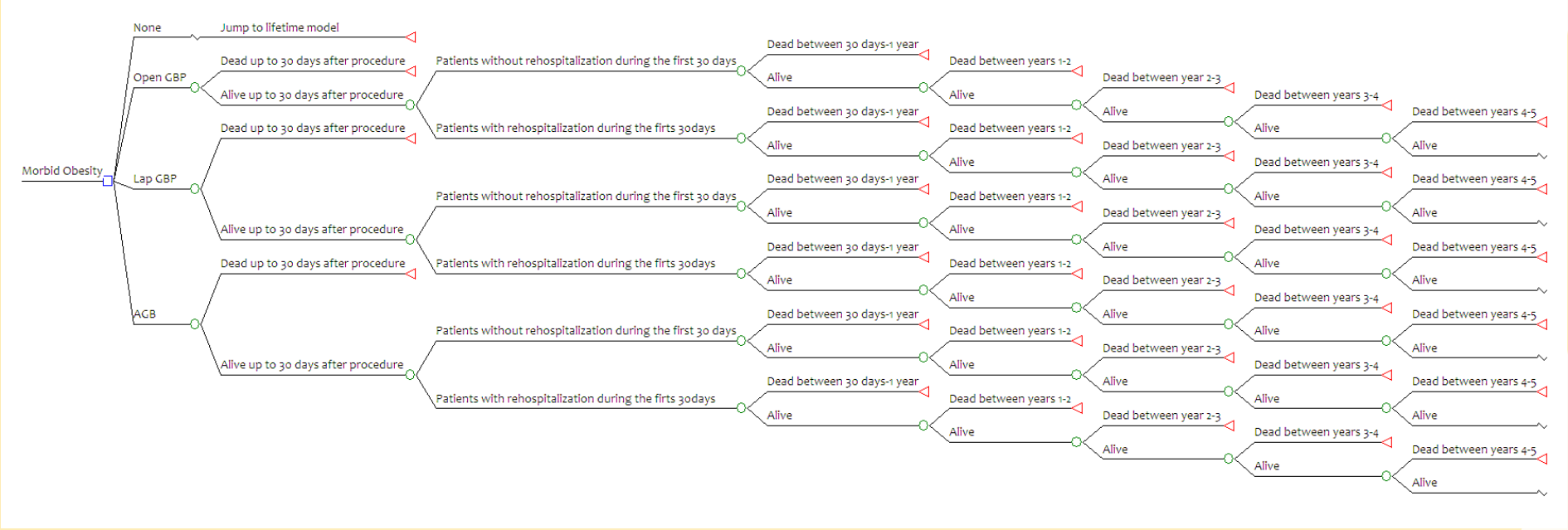
Source: BOOM Research

COMPLEXITY IN BACK-END ENGINE

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Probabilistic?																
2	0		Raw Results									Incremental	Results				
3																	
4			40.61	407,936.36	45.06	420589.35	43.98	433445.79	45.06	433242.82		4.45	12652.98	3.37	25509.42	4.45	25306.46
5																	
6			None		Lap RYGB		Band		Open RYGB			Lap RYGB		Band		Open RYGB	
7			QALYs	Cost	QALYs	Cost	QALYs	Cost	QALYs	Cost		QALYs	Cost	QALYs	Cost	QALYs	Cost
8	1		12.38	81,896.76	17.71	137150.90	16.92	152828.15	17.86	148334.29		5.33	55254.14	4.54	70931.39	5.48	66437.52
9	2		12.38	81,896.76	17.73	137370.64	16.95	149952.47	17.91	146318.10		5.35	55473.88	4.57	68055.71	5.53	64421.34
10	3		12.38	81,896.76	17.73	138010.80	16.92	153619.48	17.87	145695.80		5.35	56114.04	4.54	71722.72	5.49	63799.04
11	4		12.38	81,896.76	17.64	138254.70	17.03	147820.46	17.89	147930.12		5.26	56357.94	4.65	65923.70	5.50	66033.36
12	5		12.38	81,896.76	17.69	138104.66	17.04	148491.95	17.83	147125.93		5.31	56207.90	4.66	66595.19	5.45	65229.17
13	6		12.38	81,896.76	17.75	137963.10	17.02	149117.88	17.79	148304.02		5.36	56066.34	4.64	67221.12	5.41	66407.26
14	7		12.38	81,896.76	17.69	139159.17	17.00	149674.47	17.90	145568.35		5.31	57262.41	4.62	67777.71	5.52	63671.59
15	8		12.38	81,896.76	17.75	137308.83	17.00	148072.93	17.92	144401.36		5.37	55412.07	4.62	66176.17	5.54	62504.60
16	9		12.38	81,896.76	17.70	139398.26	16.98	151094.36	17.90	146003.25		5.32	57501.50	4.60	69197.60	5.51	64106.49
17	10		12.38	81,896.76	17.70	139726.40	17.01	150459.94	17.90	146654.35		5.32	57829.64	4.62	68563.18	5.51	64757.59
18	11		12.38	81,896.76	17.70	138511.99	17.04	147662.94	17.86	146680.86		5.32	56615.23	4.66	65766.18	5.48	64784.10
19	12		12.38	81,896.76	17.75	137335.20	17.00	150380.34	17.90	146208.23		5.37	55438.44	4.61	68483.58	5.52	64311.47
20	13		12.38	81,896.76	17.69	140288.61	17.05	147448.76	17.91	145924.71		5.31	58391.85	4.67	65552.00	5.53	64027.95
21	14		12.38	81,896.76	17.70	139343.86	17.05	147129.91	17.90	145490.05		5.32	57447.10	4.67	65233.15	5.52	63593.29
22	15		12.38	81,896.76	17.73	137679.45	17.00	150045.35	17.90	145008.22		5.34	55782.69	4.62	68148.59	5.52	63111.46
23	16		12.38	81,896.76	17.73	137616.31	17.03	147965.42	17.89	146407.81		5.35	55719.55	4.65	66068.66	5.50	64511.05
24	17		12.38	81,896.76	17.69	138837.02	17.04	148011.01	17.92	144855.58		5.31	56940.26	4.66	66114.24	5.53	62958.81
25	18		12.38	81,896.76	17.71	139207.03	17.04	147799.64	17.87	147057.26		5.33	57310.27	4.66	65902.88	5.49	65160.50
26	19		12.38	81,896.76	17.73	137902.17	17.00	150046.82	17.88	148572.45		5.35	56005.41	4.62	68150.06	5.49	66675.69
27	20		12.38	81,896.76	17.68	140689.72	17.03	147986.29	17.83	149310.89		5.30	58792.96	4.65	66089.53	5.44	67414.13
28	21		12.38	81,896.76	17.73	137525.41	16.95	150611.00	17.88	146199.93		5.35	55628.65	4.56	68714.24	5.50	64303.17
29	22		12.38	81,896.76	17.71	138761.25	17.04	147724.62	17.91	144884.97		5.32	56864.49	4.66	65827.86	5.53	62988.21
30	23		12.38	81,896.76	17.68	138210.79	17.00	147568.80	17.91	146408.92		5.30	56314.03	4.61	65672.04	5.53	64512.16
31	24		12.38	81,896.76	17.73	138196.47	17.04	147356.03	17.90	145604.96		5.35	56299.71	4.66	65459.27	5.52	63708.20
32	25		12.38	81,896.76	17.69	138673.98	16.96	150997.01	17.87	145271.01		5.31	56777.21	4.58	69100.25	5.49	63374.25
33	26		12.38	81,896.76	17.72	138971.01	17.00	148239.87	17.86	148194.02		5.34	57074.25	4.62	66343.11	5.48	66297.26
34	27		12.38	81,896.76	17.75	137406.94	17.03	148355.59	17.88	148296.96		5.37	55510.17	4.65	66458.83	5.50	66400.20
35	28		12.38	81,896.76	17.70	138519.64	17.00	149821.73	17.92	144496.42		5.32	56622.88	4.62	67924.97	5.53	62599.66
36	29		12.38	81,896.76	17.74	138822.17	17.00	148173.32	17.87	146691.09		5.36	56925.41	4.62	66276.56	5.48	64794.33
37	30		12.38	81,896.76	17.74	139659.03	17.04	149386.44	17.91	146707.78		5.36	57762.27	4.65	67489.68	5.53	64811.02
38	31		12.38	81,896.76	17.68	140111.58	16.91	148038.57	17.91	145695.97		5.30	58214.82	4.53	66141.81	5.53	63799.21

Source: BOOM Research

DECISION TREE FOR FIRST 5 YEARS

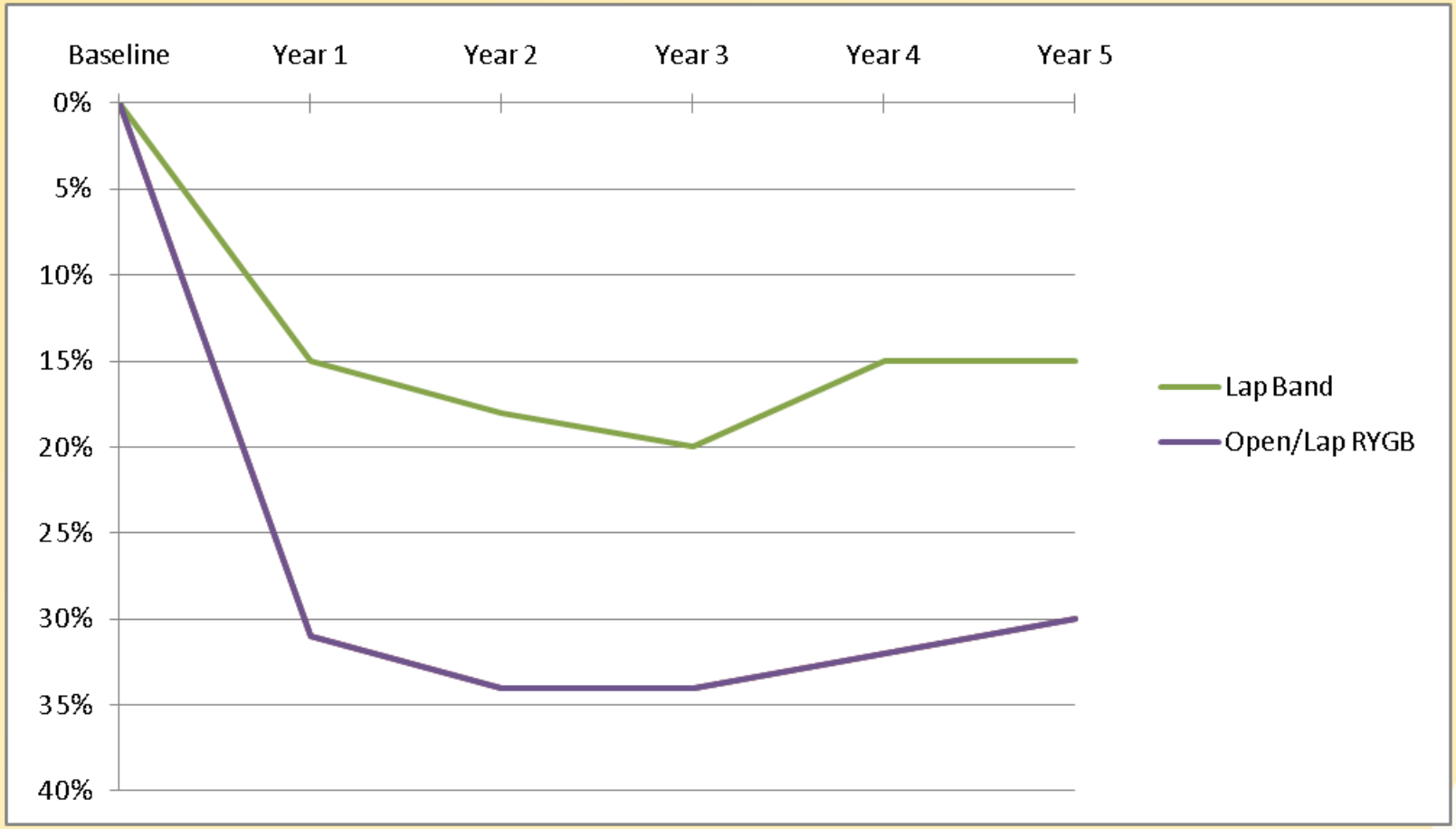


Source: BOOM Research

MANY DATA SOURCES FOR DECISION TREE

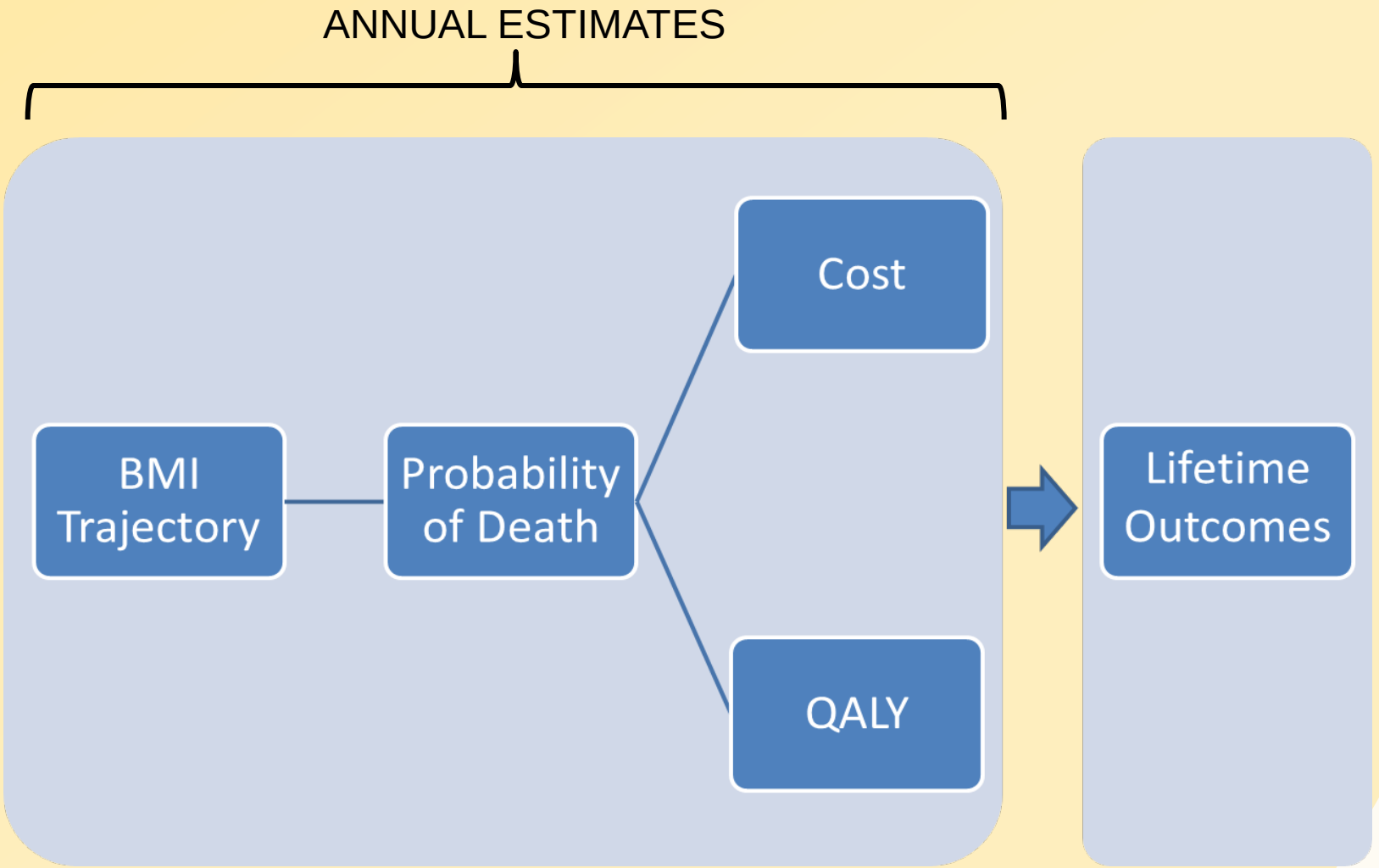
- Mortality and complication rates from Centers for Medicare & Medicaid Services (CMS)
- Annual costs from Group Health Cooperative (GHC)
- Death costs from CMS
- Utilities from Medical Expenditure Panel Survey (MEPS)
- BMI trajectory from Picot et al (HTA, 2009)

BMI LOSS IS NON-LINEAR



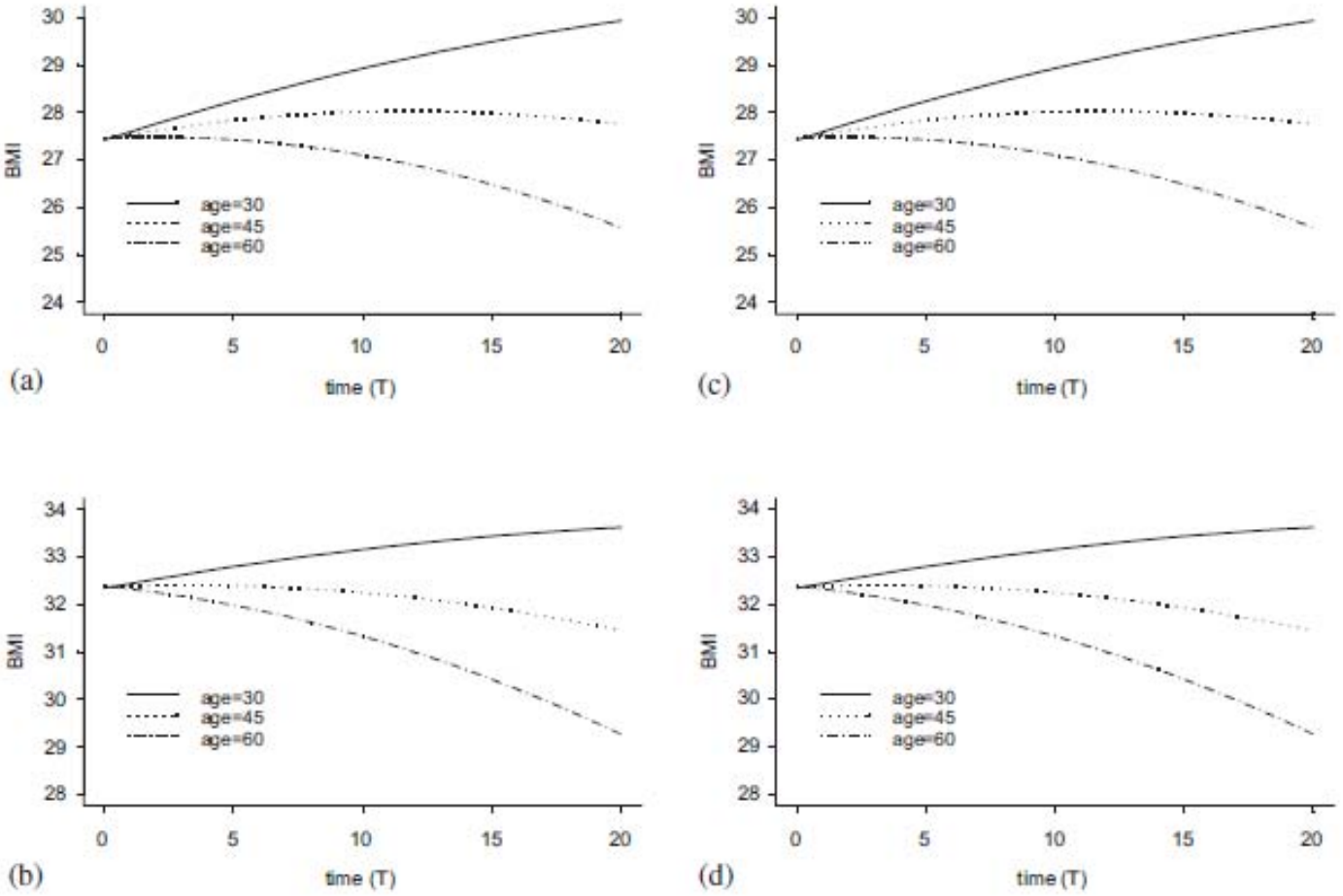
Source: Picot et al (HTA, 2009)

NATURAL HISTORY MODEL OVERVIEW



Source: BOOM Research

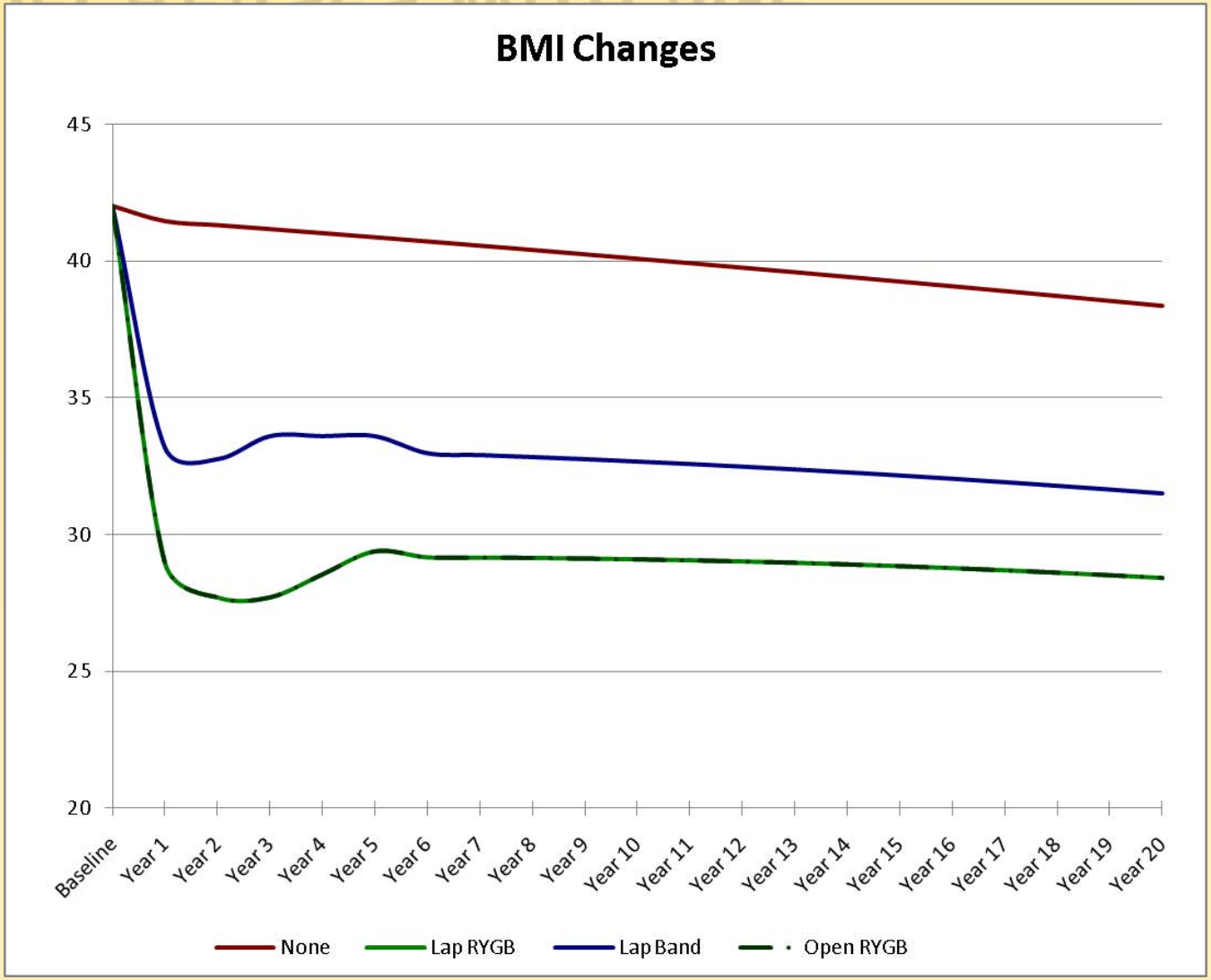
BMI TRAJECTORY FROM HEO (2003)



(*a*) for men with baseline BMI 27.5; (*b*) for men with baseline BMI 32.5; (*c*) for women with baseline BMI 27.5; (*d*) for women with baseline 32.5.

Source: Heo et al (Stat. Med., 2003)

BMI DECREASES WITH AGE



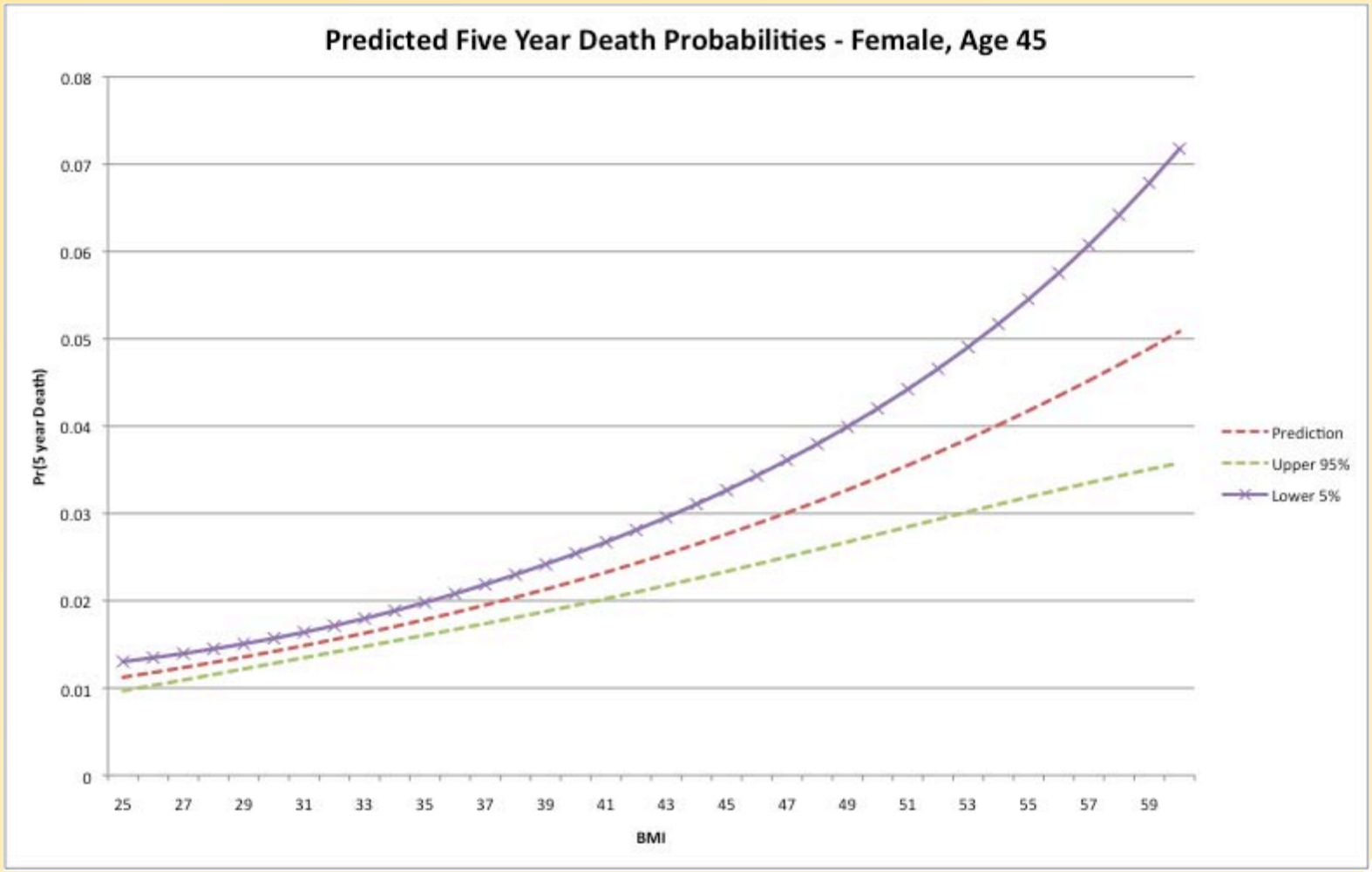
- For a Female, Age 45, BMI = 42

Source: BOOM Research

SURVIVAL MODELED FROM NHIS-NDI

- Statistical analysis adapts the methods from Schauer 2010.
- Logistic regression model is used to predict the 5-year probability of death.
- Independent variables include BMI, age, sex and interactions for sex-BMI, sex-age and BMI-age.
- Predicted death probabilities are used to generate life expectancy at any given age, sex and BMI.
- Life expectancy is computed using standard life table techniques

DEATH INCREASES WITH BMI



Source: BOOM Research

COST AND UTILITIES FROM MEPS

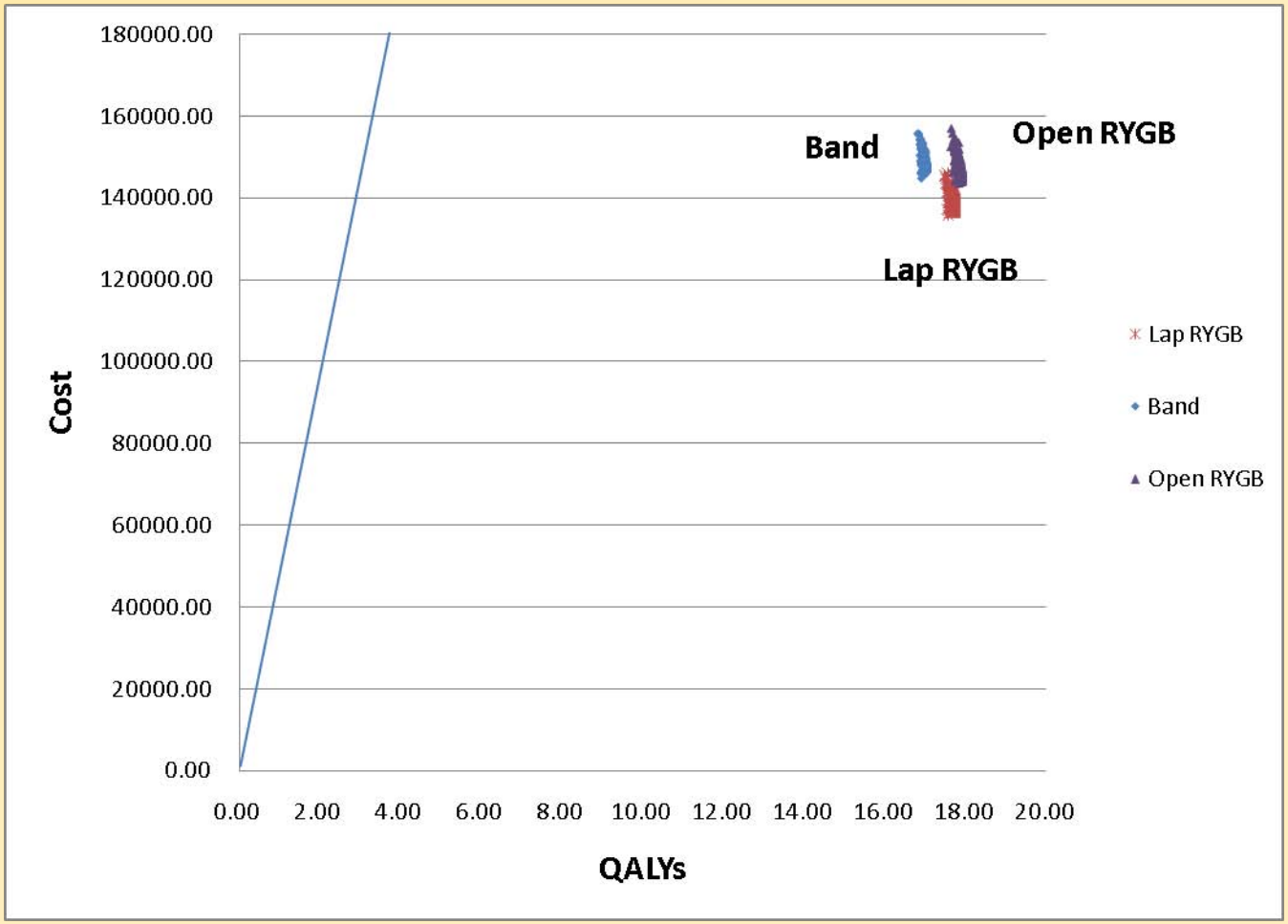
- Average annual medical costs were positively associated ($p<0.01$) with:
  - ↑ BMI (+$362 per 5 BMI unit increase),
  - ↑ Age (+$118 for each year of age), and
  - Gender (+$547 for females).
- Utility values negatively associated ($p<0.01$) with:
  - ↑ BMI (-0.0246 per 5 BMI unit increase),
  - ↑ Age (-0.0036 for each year of age), and
  - Gender (-0.0355 for females).

PREDICTED LIFETIME OUTCOMES FOR A 45-YEAR OLD FEMALE

BMI	Cost	QALY	Expected Age of Death
25	$ 155,443	21.26	83
35	$ 168,965	20.04	80
45	$ 182,149	18.81	77

Source: BOOM Research

RESULTS: EACH PROCEDURE COST-EFFECTIVE



Source: BOOM Research

VALIDATION AND SENSITIVITY ANALYSIS

- Probabilistic Sensitivity Analysis
- Model originally done in Excel
- Reproduced in SAS 9.2
- Allows for powerful simulations of large populations

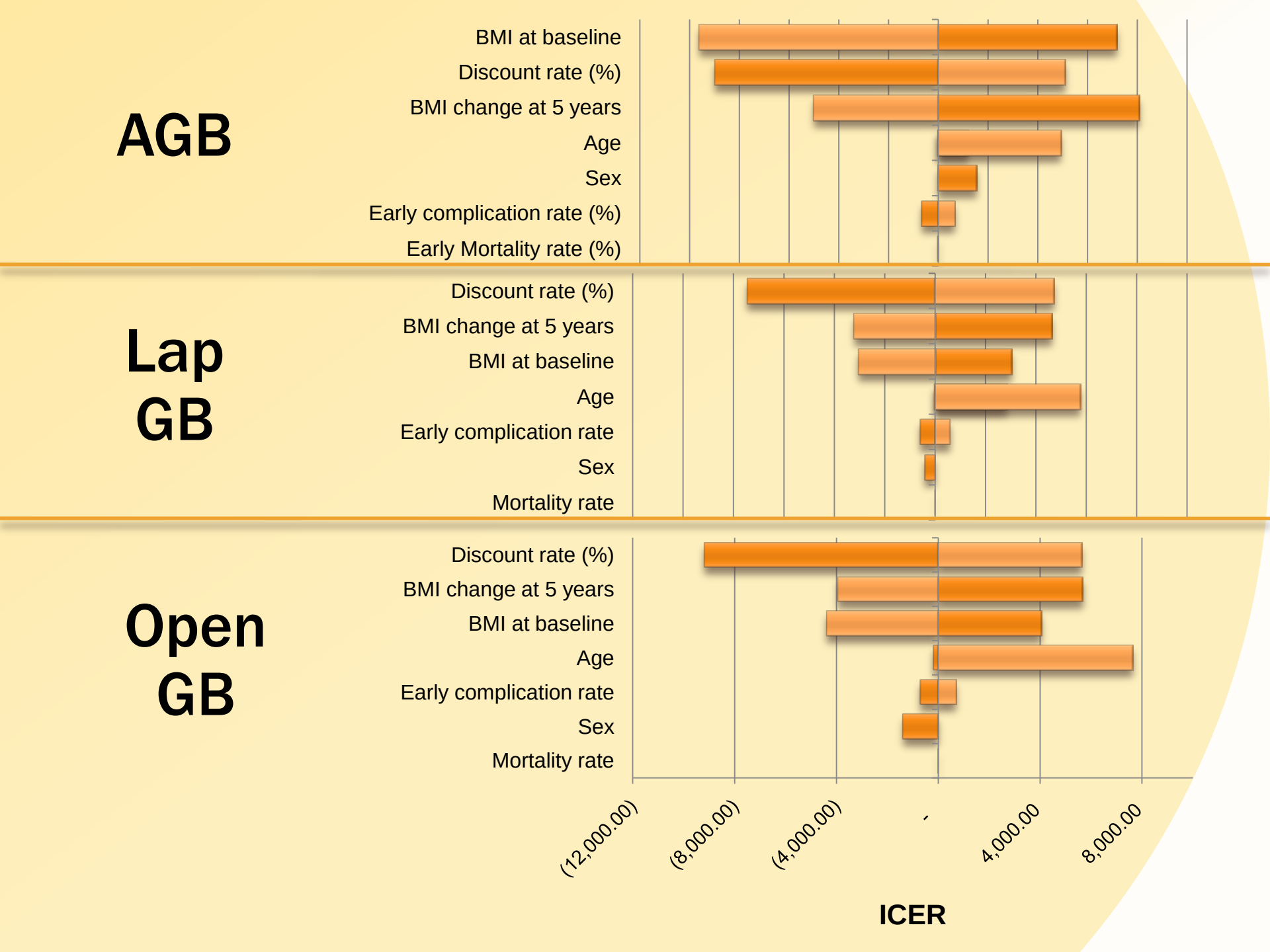
GAINS ASSOCIATED WITH BMI REDUCTION

	Cost	QALY	Life-Years
Current Population	$ 135,246	20.80	36.10
10% BMI Reduction	$ 134,313	20.90	36.30
20% BMI Reduction	$ 133,368	20.99	36.50
30% BMI Reduction	$ 132,412	21.08	36.70
40% BMI Reduction	$ 131,444	21.18	36.90
50% BMI Reduction	$ 131,400	21.21	37.10
Reduction only in those above 30 BMI			

Source: BOOM Research

ONE-WAY SENSITIVITY ANALYSIS

Variables	Reference values	Minimum	Maximum
Early Mortality rate (%)	0.23	0	0.5
Early complication rate (%)	2.5	0	5
Sex	F	M	F
Age	45	18	70
BMI change at 5 years (%)	20% AGB or 30% GB	-10%	+10%
Discount rate (%)	3	0	5
BMI at baseline	45	35	70


AGB
BMI at baseline
Discount rate (%)
BMI change at 5 years
Age
Sex
Early complication rate (%)
Early Mortality rate (%)
Lap GB
Discount rate (%)
BMI change at 5 years
BMI at baseline
Age
Early complication rate
Sex
Mortality rate
Open GB
Discount rate (%)
BMI change at 5 years
BMI at baseline
Age
Early complication rate
Sex
Mortality rate
(12,000.00)
(8,000.00)
(4,000.00)
-
4,000.00
8,000.00
ICER

PREVIOUS RESULTS

Author	Year	Population	Perspective	Interventions	ICER
Siddiqui,A., et al.	2006	Mobidly obese and super obese patients	NA	Open By-pass surgery vs. Laparoscopic By-pass Surgery	NA LGBP dominates
Van Mastrigt,G. A. et al.	2006	Morbidly obese with co-morbidity	Societal	Vertical banded gastroplasty (VBG) vs. Lap band	€36,834 Lap band dominates
Ackroyd,R. et al.	2006	Morbidly obese and type-2 diabetes, in Germany, UK and France	Payer	AGB and GBP vs no intervention	Germany: €-1,305 for AGB €-2,208 for GBP France: €1,379 for AGB €-4,000 for GBP UK £3,251 for AGB £2,599 for GBP
Salem,L. et al.	2008	Morbidly obese without obesity-related comorbidities	Payer	AGB and LRYGB and no intervention	$8,878 for AGB $14,680 for LRYGB
Campbell et al.	2010	Mobidly Obese US	Payer	AGB and LRYGB and no intervention	$/LY $9,300 for AGB $10,600 for LRYGB

AGB: Adjustable gastric banding
LRYGB: laparoscopic Roux-en-Y gastric bypass

A Financial Model of Bariatric Surgery for Morbid Obesity

Rafael Alfonso-Cristancho, MD, MSc

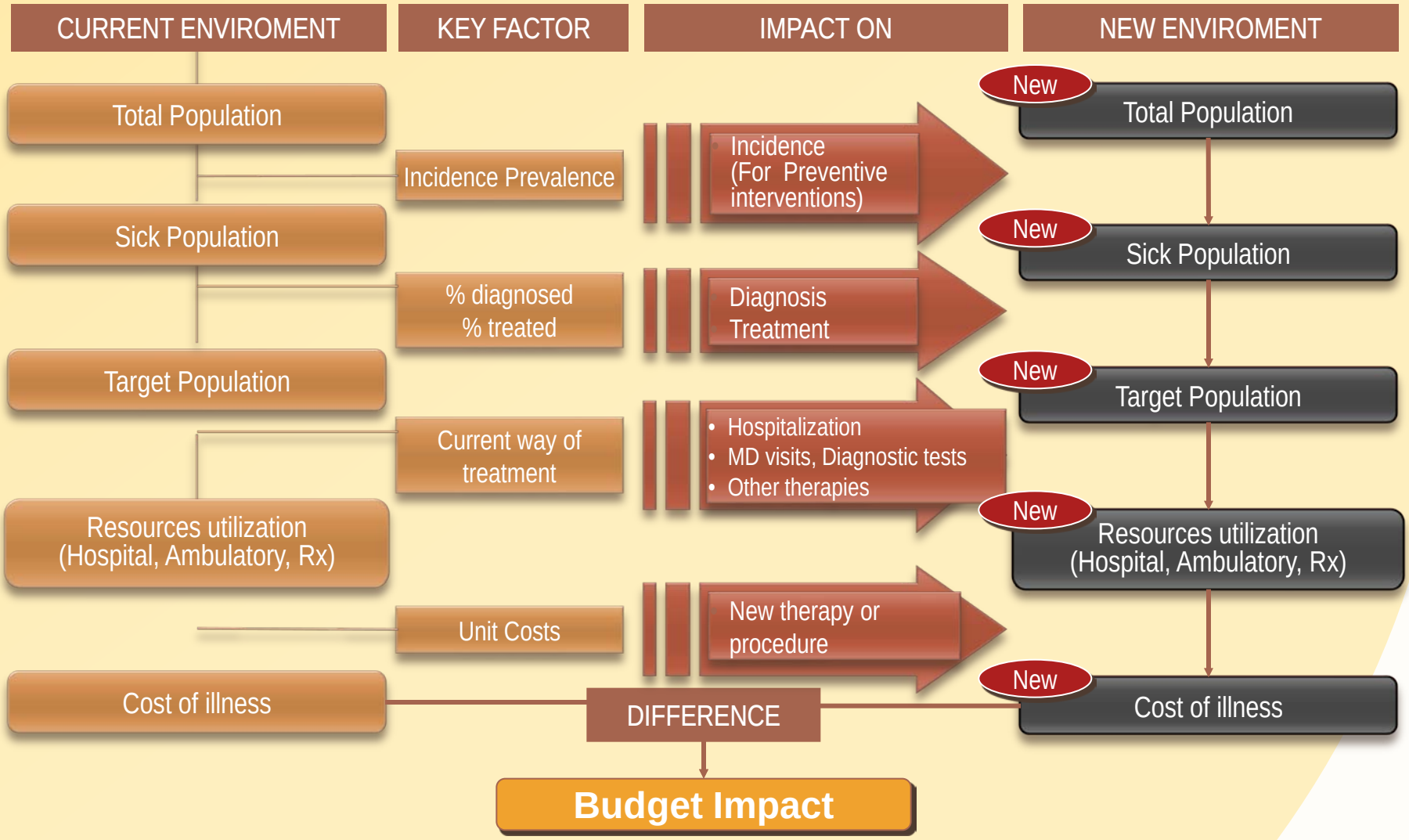
WHAT IS A BUDGET IMPACT ANALYSIS?

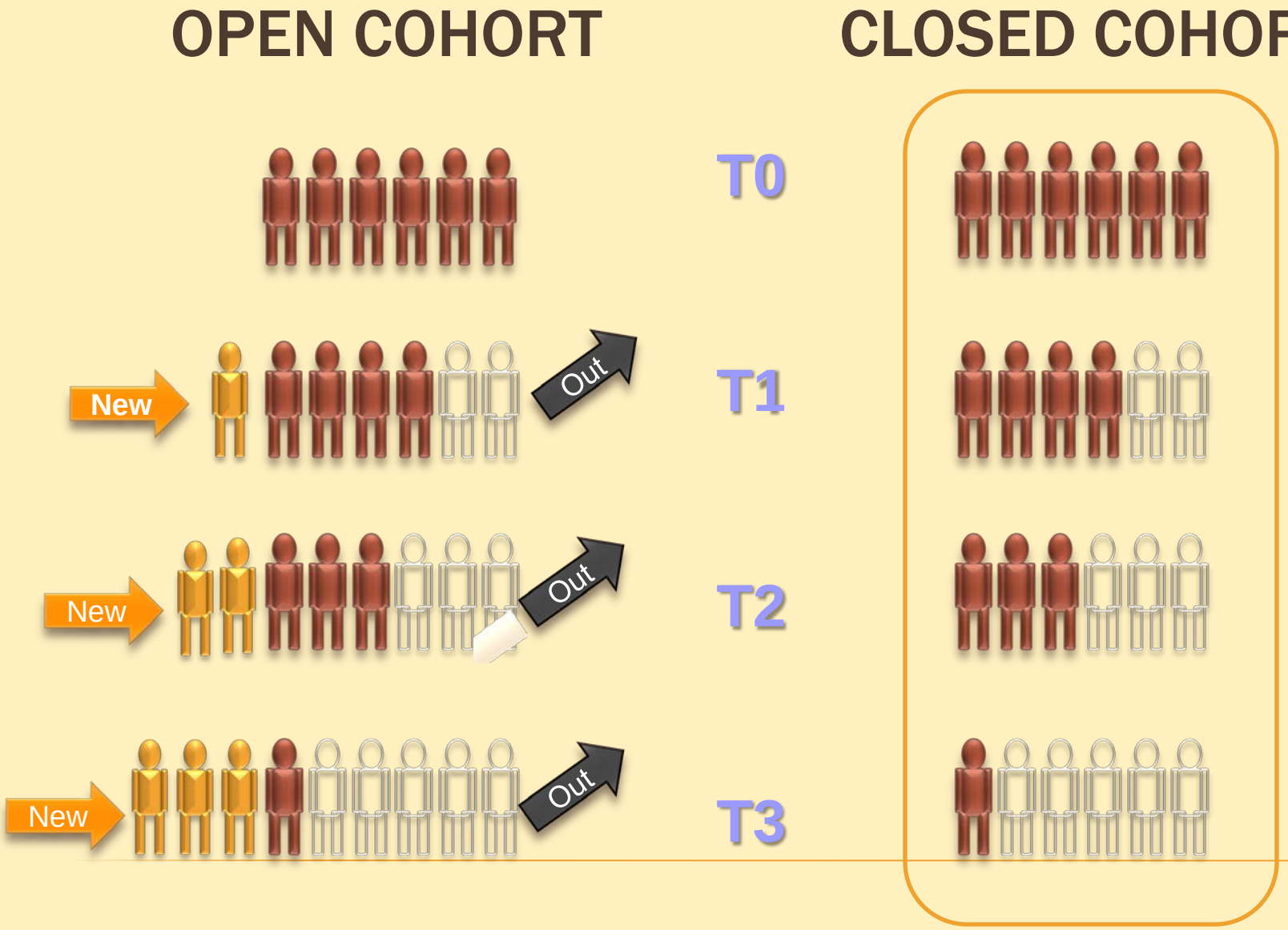
"The purpose of a Budget Impact Analysis is to estimate the financial consequences of adoption and diffusion of a new health care intervention within a specific health care setting or system context given inevitable resource constraints."

A Budget Impact Model (BIM) was developed to perform this analysis

Mauskopf JA, Sullivan SD, Annemans L, et al. Principles of Good Practice for Budget Impact Analysis: Report of the ISPOR Task Force on Good Research Practices – Budget Impact Analysis. ***Value in Health*** 2007;10;336-47

HOW THE BIM IS DEVELOPED?




OPEN COHORT
CLOSED COHORT
T0
T1
T2
T3
New
Out
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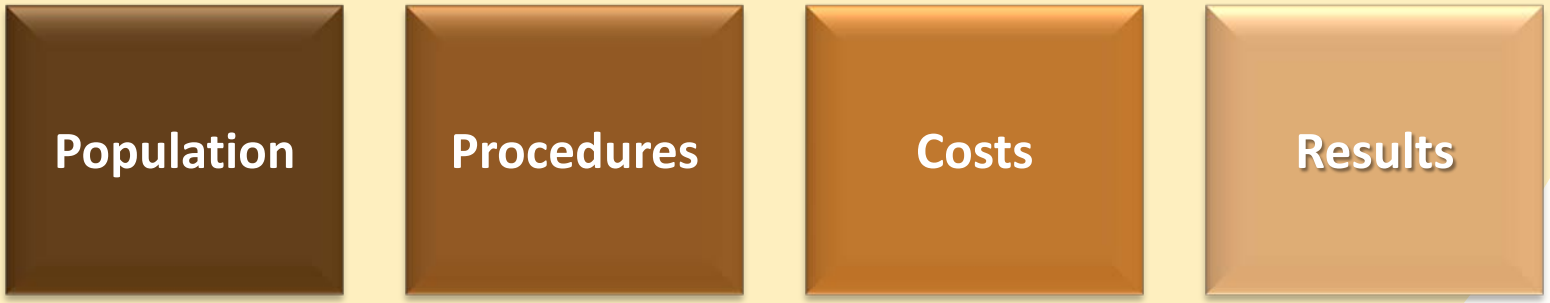
Out

BUDGET IMPACT MODEL



PATIENTS ELIGIBLE FOR BARIATRIC SURGERY IN GIVEN YEAR*

	Females		Males		Total	
	N	%	N	%	N	%
BMI >35&<40 with comorbidities	30,553	5.7%	13,087	2.8%	43,639	4.4%
BMI >40	29,979	5.6%	9,636	2.1%	39,615	4.0%
Total number of patients	60,532	11.4%	22,723	4.9%	83,254	8.3%

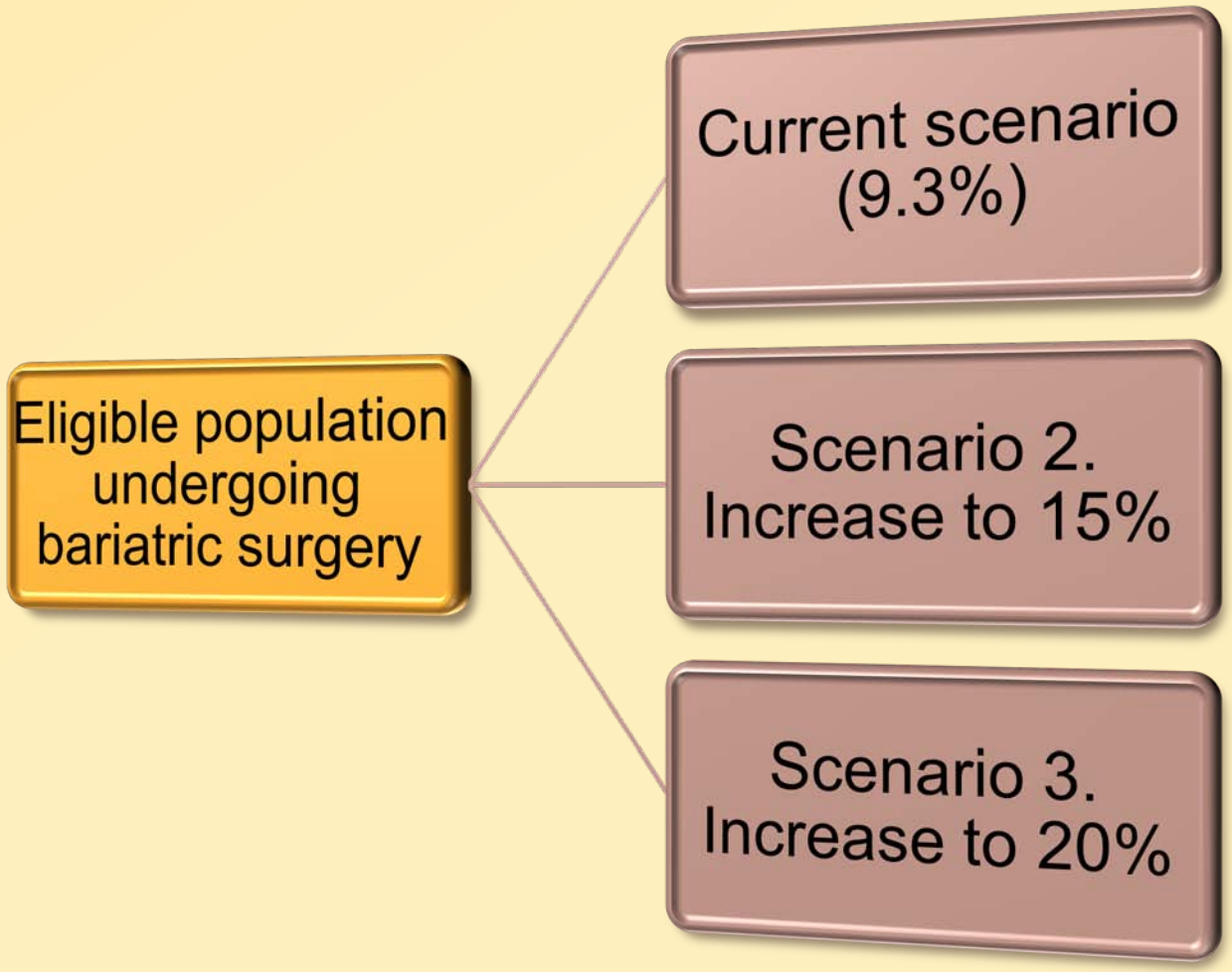
* Based on a hypothetical closed cohort of 1 million subjects with the same age, gender and BMI distribution as reported by NHANES

POPULATION*

- **U.S. General Population**
  - Approx. 307 million (July 2009)
  - 5.7% of adult population (Approx. 14 million people) had a BMI>40 kg/m2 (NHANES)
  - 171,000 bariatric surgeries were performed in 2005 (ASBS)
- **TRI-CARE**
  - Approx. 9.4 million beneficiaries (DEERS)
  - Air Force (AF) Active Duty (AD) (2001-2007): 608,939
    - Had bariatric surgery: 49 (< 0.01%)
    - Had morbid obesity and no bariatric surgery: 4,430 (0.7%)
  - AF beneficiaries (not AD anytime from 2001-2007): 1,575,257
    - Had bariatric surgery: 6,964 (0.5%)
    - Had morbid obesity and no bariatric surgery: 63,863 (4.1%)

**Closed cohort*

SCENARIOS FOR ANALYSIS



PROCEDURE MIX

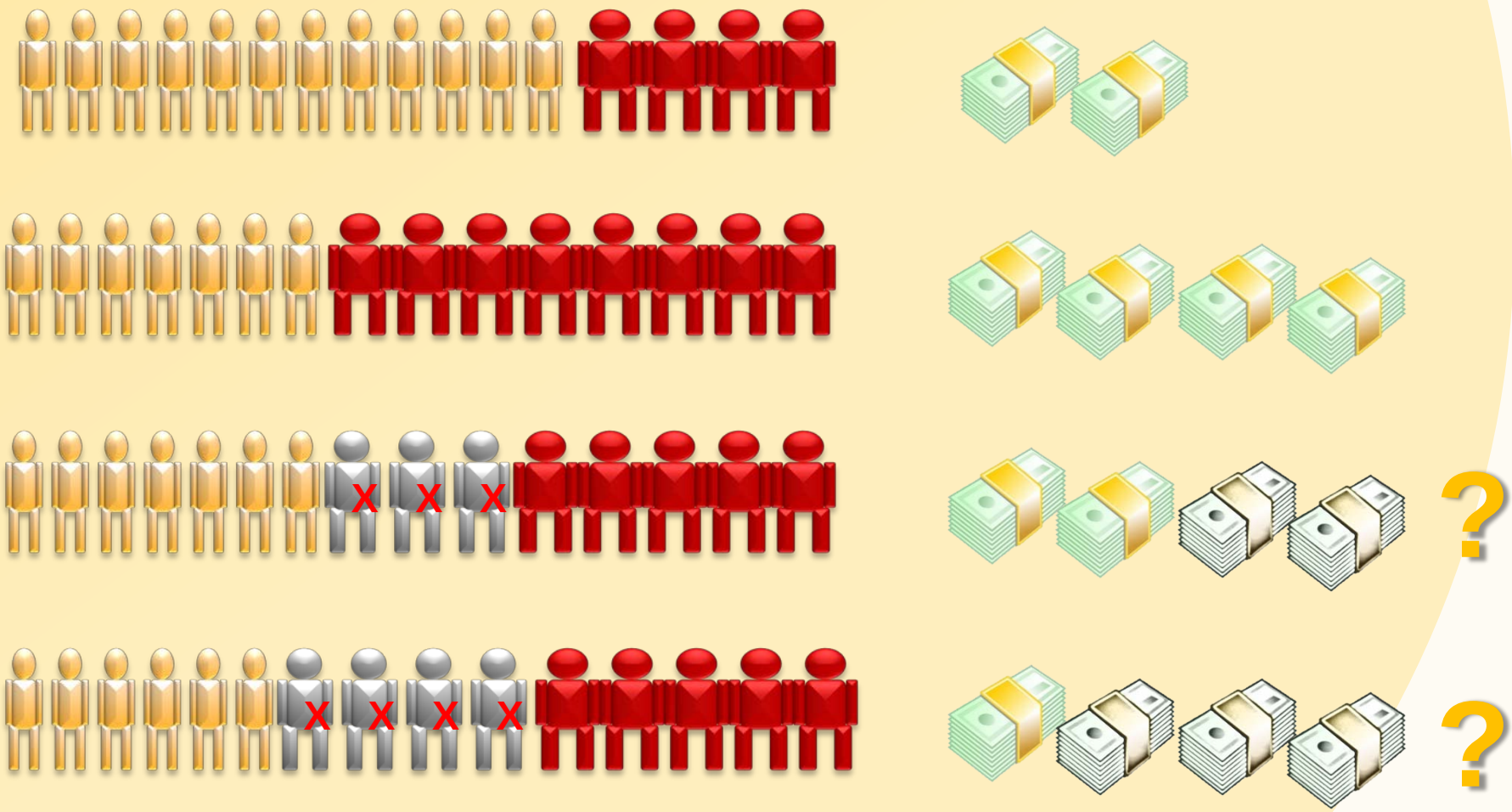
- AD+Beneficiaries: 2,184,196
- Approx. 75,306 (3.4%) with morbid obesity
- Only 9.3% of morbidly obese underwent bariatric surgery .

AF reference population

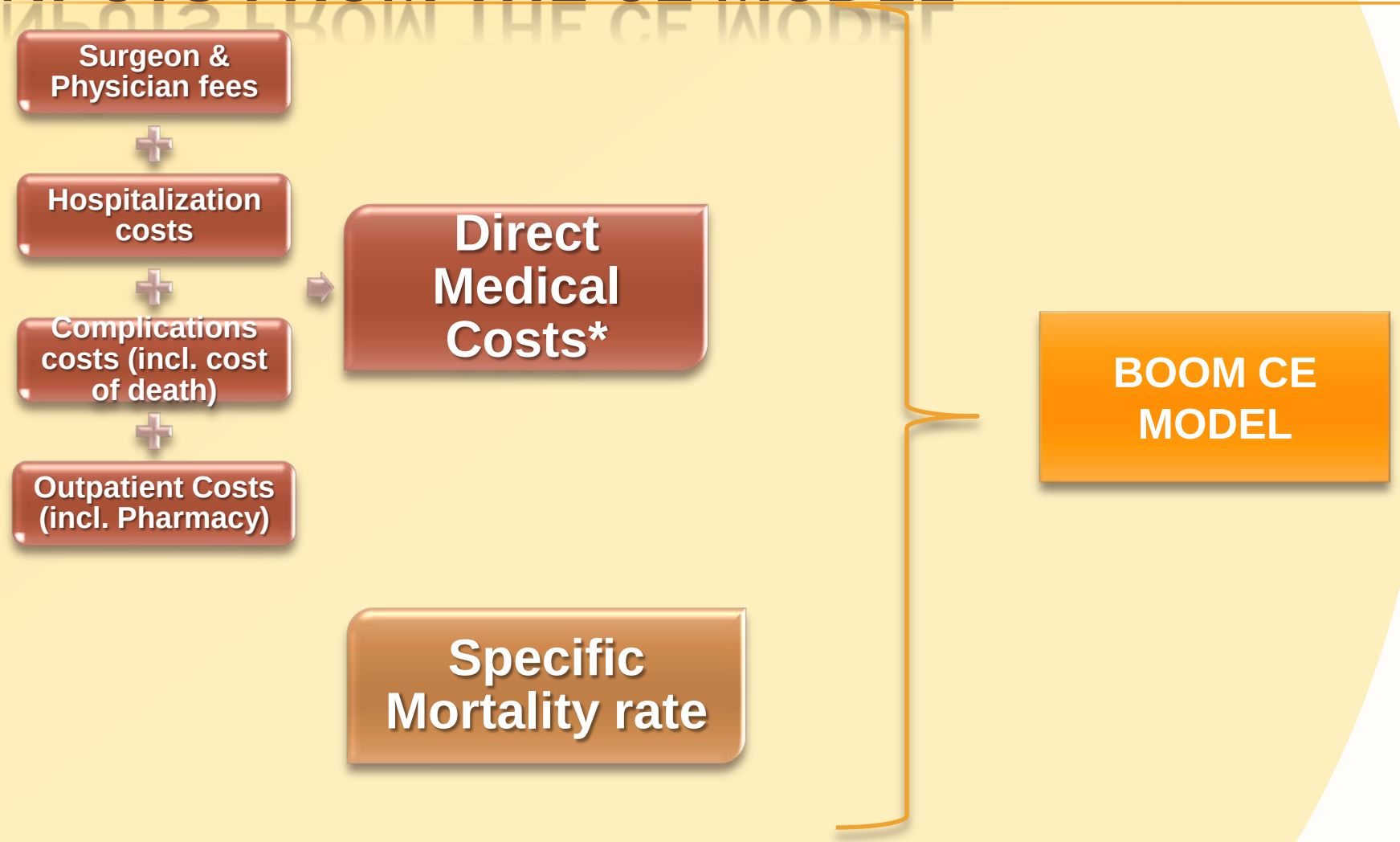
% of bariatric surgery for eligible patients	Scenario 1 (9.3% - current)		Scenario 2 (15%)		Scenario 3 (20%)	
Procedures	N	%	N	%	N	%
Lap RYGB	4,208	60	6,684	60	8,912	60
AGB	701	10	1,114	10	1,485	10
Open RYGB	2,104	30	3,342	30	4,456	30
Sleeve	-	-	-	-	-	-
Biliopancreatic Div	-	-	-	-	-	-
Total	**7,013**	**100**	**11,140**	**100**	**14,853**	**100**

Data on file from the BOOM Study Group at UW

HOW MUCH DOES OBESITY COST?
HOW MUCH DOES BARIATRIC SURGERY COST?



INPUTS FROM THE CE MODEL



Source: BOOM Cost-Effectiveness Model-Reference case: 40 y.o. Female BMI=42 kg/m2

DIRECT MEDICAL COSTS (SELECTED YEARS)

Average Annual Direct Medical Costs

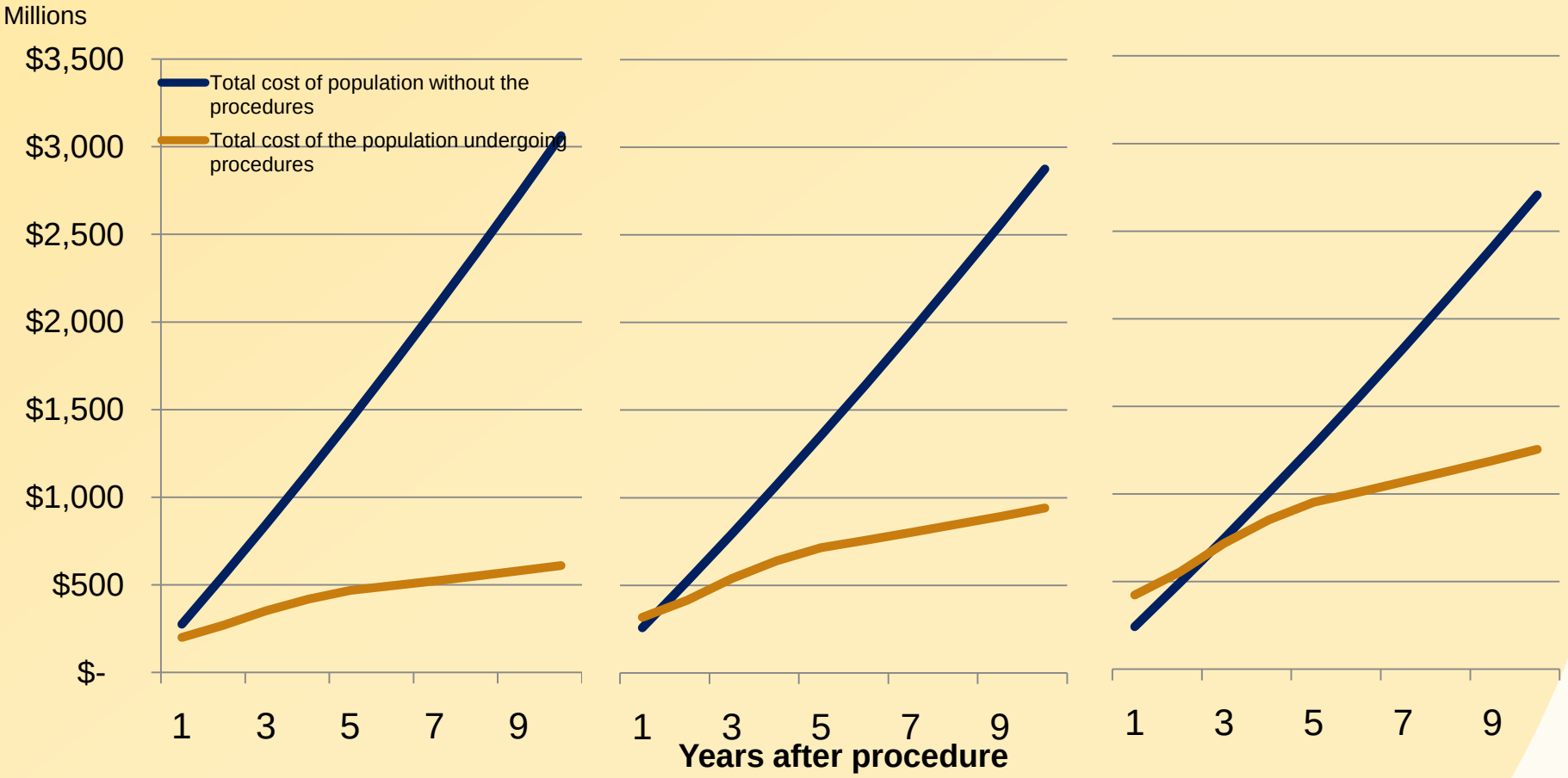
	Year 1	Year 3	Year 5	Year 7	Year 9	Year 10
None	$ 4,101	$ 4,314	$ 4,525	$ 4,736	$ 4,945	$ 5,048
Lap RYGB	$ 30,222	$ 10,451	$ 5,378	$ 3,928	$ 4,159	$ 4,274
Lap Band	$ 19,133	$ 15,653	$ 10,526	$ 4,194	$ 4,416	$ 4,526
Open RYGB	$ 30,176	$ 13,237	$ 9,403	$ 3,928	$ 4,159	$ 4,274

Source: BOOM Cost-Effectiveness Model-Reference case: 40 y.o. Female BMI=42 kg/m2

DIRECT MEDICAL COSTS BY SCENARIO BY YEAR (SELECTED YEARS)

		Total cost of the population without the procedures	Total cost of the population undergoing procedures	Total plan costs	Incremental PMPY
Scenario 1 (9.3% Current)	Year 1	$ 274,855,100	$ 199,961,200	$474,816,300	$ 79
	Year 5	$ 302,967,900	$ 47,141,300	$350,109,200	$ 7
	Year 10	$ 337,441,800	$ 30,006,300	$367,448,100	$ (3)
Scenario 2 (15%)	Year 1	$ 257,988,400	$ 317,637,900	$575,626,300	$ 126
	Year 5	$ 284,376,000	$ 74,883,900	$359,259,900	$ 12
	Year 10	$ 316,734,400	$ 47,664,900	$364,399,200	$ (4)
Scenario 3 (20%)	Year 1	$ 242,812,600	$ 423,517,200	$666,329,800	$ 167
	Year 5	$ 267,648,000	$ 99,845,100	$367,493,100	$ 16
	Year 10	$ 298,103,000	$ 63,553,200	$361,656,100	$ (5)

RESULTS: CUMULATIVE PLAN COST BY INTERVENTION



CONCLUSIONS

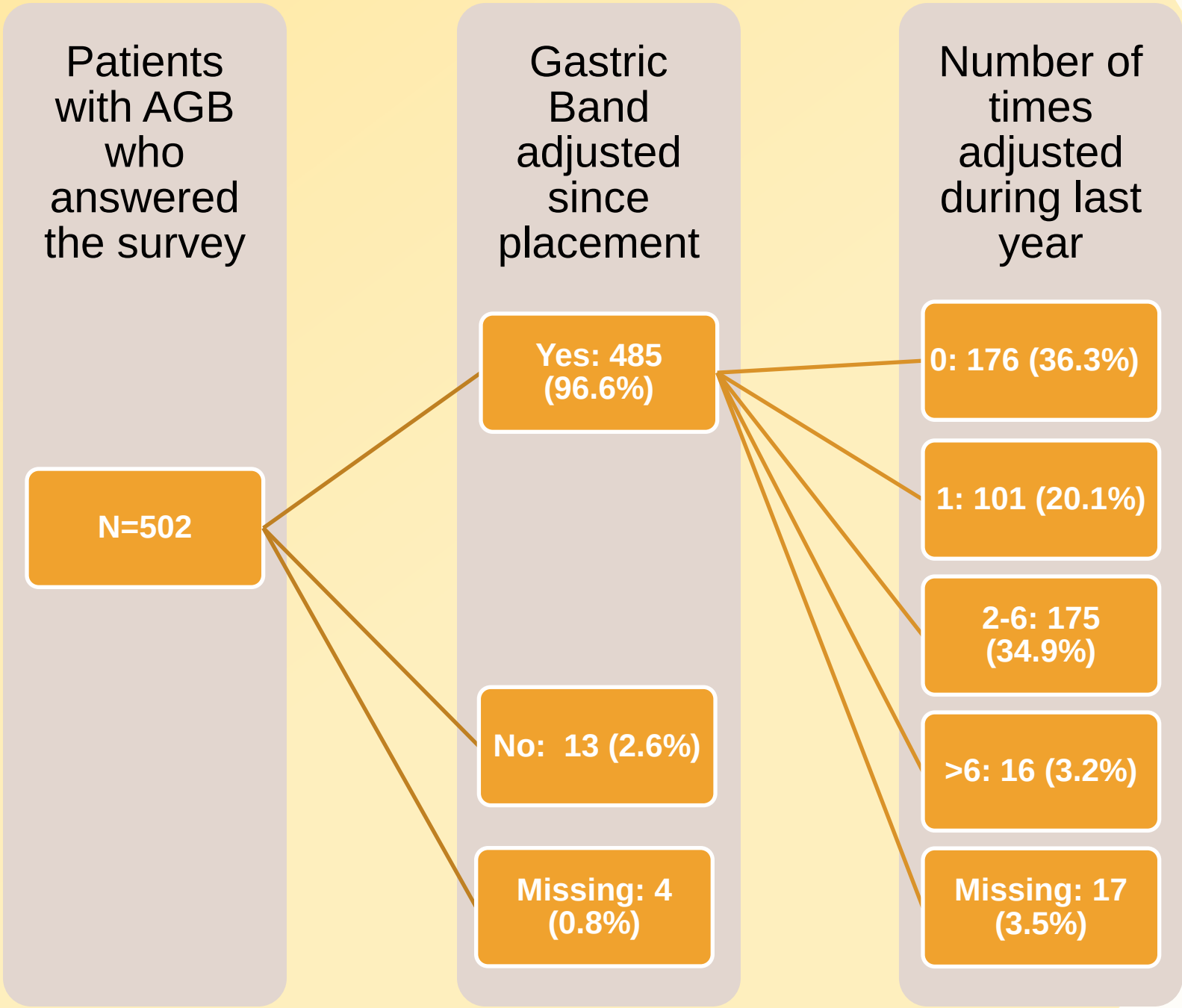
- In the three scenarios examined, the Incremental PMPY becomes negative after year five, leading to savings in direct medical costs .
- By the end of the 10-year period, the highest cumulative costs are for the scenario where no one receives surgery.
- The results are driven by the number of subjects receiving each of the different procedures and the costs associated with each one over time.
- The model allows for customization of each parameter to provide useful estimates for the decision-maker: nevertheless, additional benefits not included in the model--such as increased life expectancy, quality of life, and productivity, among others--should be considered during the decision-making process.

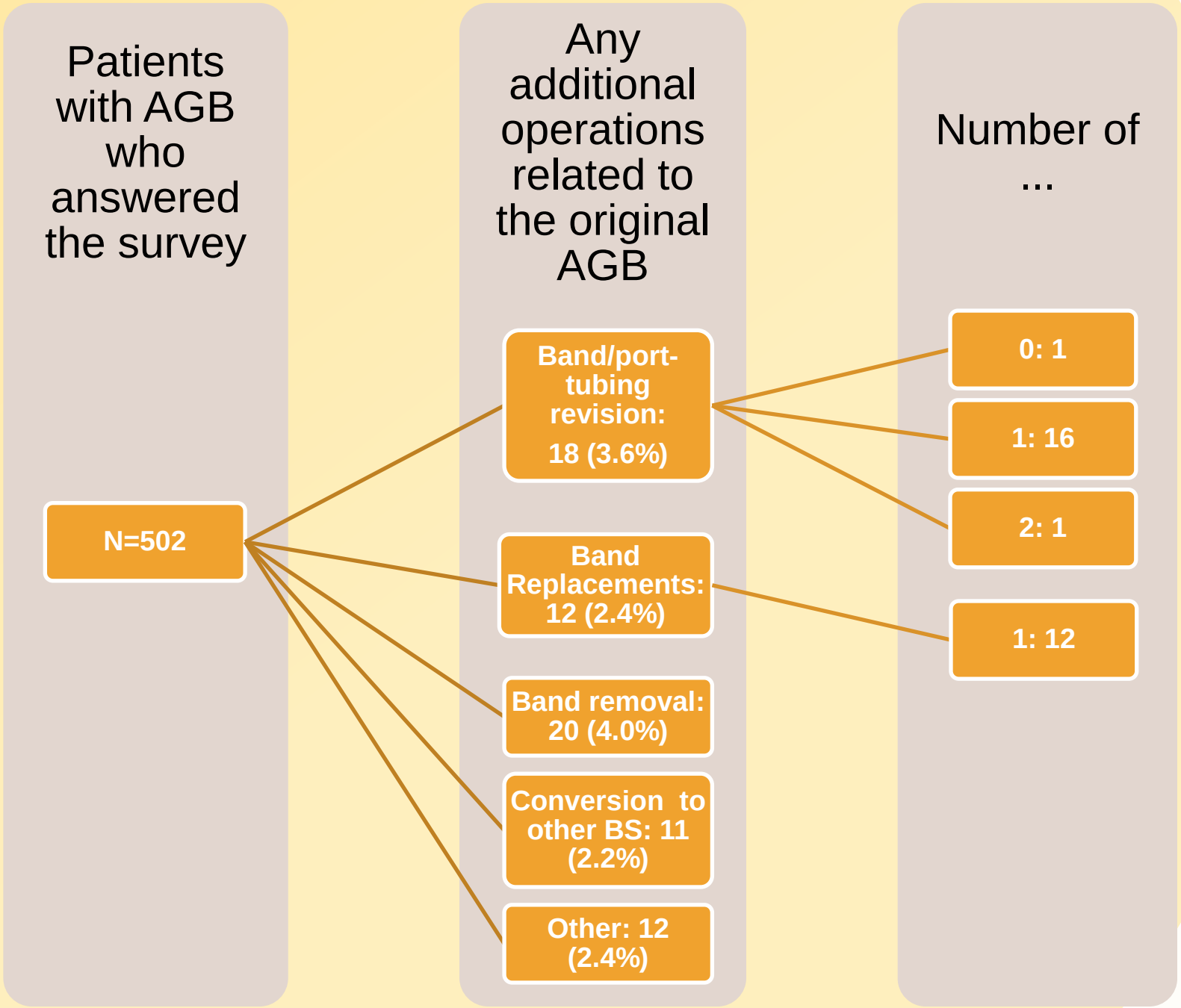
AGB Survey Study

David Flum, MD, MPH, Co-Principal Investigator

AGB SURVEY STUDY

- Objective: To capture the semi quantitative and use/frequency of follow-up care for AGB patients.
- Surveyed 1,571 patients who had AGB between April 1, 2007 and July 1, 2008 at four sites in Washington State
- Patients completed the AGB Health Survey and EQ5D
- Response: 502 surveys (32% response)


Patients with AGB who answered the survey
N=502
Gastric Band adjusted since placement
Yes: 485 (96.6%)
No: 13 (2.6%)
Missing: 4 (0.8%)
Number of times adjusted during last year
0: 176 (36.3%)
1: 101 (20.1%)
2-6: 175 (34.9%)
>6: 16 (3.2%)
Missing: 17 (3.5%)


Patients with AGB who answered the survey
N=502
Any additional operations related to the original AGB
Band/port-tubing revision: 18 (3.6%)
Band Replacements: 12 (2.4%)
Band removal: 20 (4.0%)
Conversion to other BS: 11 (2.2%)
Other: 12 (2.4%)
Number of ...
0: 1
1: 16
2: 1
1: 12

Research Outcomes

David Flum, MD, MPH, Co-Principal Investigator

Sean Sullivan, PhD, Co-Principal Investigator

PRESENTATIONS AND PUBLICATIONS

- **Projecting the economic outcomes of obesity using a natural history model.** Poster presented at ISPOR - International Society for Pharmacoeconomics and Outcomes Research: 15th Annual International Meeting. *May 15-19, 2010. Atlanta, GA*
- **Budget Impact Analysis of Bariatric Surgery for Morbid Obesity.** Presentation at AFMS Medical Research Symposium. *August 24-26, 2010. Arlington, VA*
- **The Impact of Medicare's Accreditation-based National Coverage Decision on the Use, Safety and Cost of Bariatric Surgery Among Medicare Beneficiaries**. *Publication prepared for* Health Affairs *and* Annals of Surgery

Implications for DOD Policy